



Volume 15, Issue 1

November 2016 – January 2017

Pharmacy Benefits Management- Medical Advisory Panel- VISN Pharmacist Executives E_z - MINUTES

Watch for the next issue of Ez-Minutes Tuesday, May 2nd, 2017

See us at: <http://www.pbm.va.gov/> or <https://vaww.cmopnational.va.gov/cmop/PBM/default.aspx>.

Welcome Mitchell Nazario, PharmD, National PBM Clinical Pharmacy Program Manager-Pain Management & Substance Abuse

Please Note: The [PBM Internet Site](#) is currently being updated. Documents from October 2016 to present are in the process of being posted. The VAMedSAFE Documents Section in Ez Minutes will resume next issue. We regret any inconvenience for the delay.

Inside This Issue

[Posting of National PBM Documents](#) Nov 2016 – Jan 2017

[National Contract Awards for CY 2016](#)

[Pharmacy-Prosthetics-Logistics and Acquisitions \(PPL\) Workgroup](#) October-November 2016

[Low Utilization of Hydralazine and Isosorbide Dinitrate for](#)

[Heart Failure in African American Veterans](#)

[DOACs in Obesity](#)

NEW! PEARLS for PACT PROVIDERS

[PBM-MAP-VPE Monthly Webinar: STATs Series Next](#)

Note: New Start Time 3:10 PM ET

The purpose of PBM-MAP-VPE Ez-Minutes Newsletter is to communicate with the field on items which will impact clinical practice in the VA. Please send and feedback and/or comments to Janet.Dailey@VA.gov.

The recent issue of Ez Minutes can be read from your smart phone! Put the below link in your browser; hit search... and the current issue from the PBM INTERnet site is ready to read. <http://www.pbm.va.gov/PBM/ezminutes/current/currentEzMinute.pdf>

Don't forget...you can also subscribe to Ez-Minutes and any documents posted to the What's New Section on the PBM INTERnet web site by subscribing to the RSS Feed. <http://www.pbm.va.gov/PBM/rss/WhatsNewAtPBMRSSFeed.xml>

Posting of National PBM Documents Nov 2016 – Jan 2017 Formulary Decisions

ADDED to the VA National Formulary (VANF)	NOT ADDED to the National Formulary (VANF)	Removed from the National Formulary (VANF)
<ul style="list-style-type: none"> Carfilzomib Difluprednate- Restricted to approved indications and authorized prescribers Esomeprazole Injection Meningococcal B vaccine (Bexsero)- Restricted to ACIP recommendations Olopatadine 0.7% - *PA-F for patient who do not respond to or have had an adverse event to ketotifen Trospium Immediate Release Viekira XR (replaces Viekira Pak) <p>*PA-F-Prior authorization at facility level</p>	<ul style="list-style-type: none"> Aspirin/Omeprazole Betamethasone Dipropionate Topical Spray Cariprazine Dacizumab Daratumumab Elotuzumab Eslicarbazepine Eslicarbazepine Ixazomib Lansoprazole Delayed-release Orally Disintegrating Tablets Lesinurad Lifitegrast Lisinopril oral solution Meningococcal B Vaccine (Trumenba) Methylnaltrexone Miltefosine Naltrexone ER/Bupropion ER Pimavanserin Sotalol hydrochloride injection Tofacitinib Extended-release Tablet Venetoclax 	<ul style="list-style-type: none"> Aripiprazole Immediate-acting IM injection Finasteride 1mg Viekira Pak
Criteria for Use (CFU)		
<ul style="list-style-type: none"> Anticoagulants, Direct Oral (DOACs) CFU and Algorithm for Nonvalvular Atrial Fibrillation [Updated Dec. 2016] Anticoagulants, DOACs CFU for Venous Thromboembolism (VTE) Prophylaxis in Ortho Surgery [Updated Dec. 2016] Anticoagulants, DOACs CFU and Algorithm for VTE Treatment [Updated Dec. 2016] Atezolizumab PA-F Biologics in Psoriasis and Psoriatic Arthritis [Updated Nov 2016] Carfilzomib Daclatasvir and Sofosbuvir [Updated Nov. 2016] Dacizumab Daratumumab Elotuzumab Enzalutamide [Updated Nov. 2016] Ixazomib Lesinurad Lifitegrast Methylnaltrexone Injection and Tablet [Updated Jan. 2017] Naltrexone ER /Bupropion ER Pimavanserin Rifaximin for Hepatic Encephalopathy [Updated Dec 2016] Simeprevir plus Sofosbuvir [Updated Nov. 2016] Sofosbuvir-VEL and Ledipasvir-Sofosbuvir [Updated Nov. 2016] 		
Abbreviated Review	Drug Monograph	
<ul style="list-style-type: none"> Meningococcal B Vaccines MenB-4C (Bexsero) and MenB-FHbp (Trumenba) 	<ul style="list-style-type: none"> Afatinib [Updated Dec. 2016] Betamethasone Dipropionate Topical Spray Cariprazine Dacizumab Daratumumab Elotuzumab Eslicarbazepine Lesinurad Lifitegrast Methylnaltrexone Tablets Naltrexone ER/Bupropion ER Pimavanserin Venetoclax 	
Clinical Recommendations		
<ul style="list-style-type: none"> Beta-Blockers in Heart Failure, Clinical Recommendations [Updated Dec. 2016] Hydralazine and Isosorbide Dinitrate in African Americans with Heart Failure, Clinical Recommendations [PBM INTRANet site only] Type 2 Diabetes Glucose-Lowering Drug Selection Guidance [PBM INTRANet site Only] 		

National Contract Awards for Calendar Year 2016

Click on [this link](#) to view the National Contract Awards CY 2016. [InTRANet only]

Pharmacy-Prosthetics-Logistics (PPL)* Workgroup

The table below depicts the various products reviewed during October - November 2016 meetings. The X marks which service(s) is responsible for managing the respective products. Click [HERE](#) for recommendation and minutes made from earlier meetings.

*The PPL workgroup was created to help clarify the responsibility for management (e.g., ordering, storing, purchasing, and/or dispensing) of those products in which it is not clear which service should provide. The workgroup is not responsible for determining formulary status, clinical merit, or appropriate use of the products reviewed.

Products	Pharmacy+	Prosthetics+	Logistics+
Insulin teaching/training supplies			X (inpatients and clinic use)
Insulin coolers for appropriately identified homeless Veterans	X		
VBLOC Neurometabolic Therapy or similar product		X	
AspireAssist or similar product		X	
Electromist conduction spray or similar products (after initial supply is provided by prosthetics with electro-stimulating device)	X (outpatients)		X (inpatients or clinic use)

+ Contingent upon approval from VISN or local Clinical Products Review Committee (CPRC). Implementation of these recommendations should be coordinated between services at local sites to ensure a smooth transition if recommendations lead to a change in responsible service. If you have any questions related to this announcement, please contact the responsible local service (Pharmacy, Prosthetics, or Logistics) for more detailed

Low Utilization of Hydralazine and Isosorbide Dinitrate for Heart Failure in African American Veterans

BACKGROUND: It has been estimated that nearly 5% of the Veteran population receiving care at the VA has a primary diagnosis of heart failure (HF). In addition, approximately 16% of patients with HF report race as black or African American (per PBM internal review of Veteran medication users).

The VA PBM Services and VA MedSAFE evaluated the treatment of HF with reduced ejection fraction (HFrEF) in African American Veterans to determine whether a disparity in medication management existed in this patient population. Per a preliminary database evaluation (conducted prior to the availability of sacubitril/valsartan or ivabradine) of the pharmacologic treatment of HF based on race, there is a comparable percent of black and white patients with HF receiving guideline-directed medical therapy including an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin II receptor antagonist (ARB), beta-blocker, or aldosterone antagonist.

GUIDELINE RECOMMENDATIONS: The 2013 American College of Cardiology Foundation (ACCF)/American Heart Association (AHA) HF guidelines has the following pharmacologic treatment recommendations for HFrEF based on race:

Hydralazine and Isosorbide Dinitrate: Class I Recommendation; Level of Evidence A

The combination of hydralazine and isosorbide dinitrate is recommended to reduce morbidity and mortality for patients self-described as African Americans with NYHA [New York Heart Association] class III-IV HFrEF receiving optimal therapy with ACE inhibitors and beta blockers, unless contraindicated.

EVALUATION OF UTILIZATION: According to a VA MedSAFE evaluation of the PBM database for fiscal year 2015 (FY15), of the patients with HF receiving treatment with hydralazine and isosorbide dinitrate, these medications were prescribed more frequently in black patients (63%) than white patients (37%). Also according to the VA MedSAFE evaluation, approximately 4% of black or Veterans with HF received hydralazine and isosorbide dinitrate in FY15. This appears to be only slightly lower than seen in other reports; and per recent publications in the medical literature, there continues to be low utilization of hydralazine and isosorbide dinitrate in the U.S. in eligible patients with HF.

CONCLUSIONS: From the preliminary PBM database evaluation conducted by VA MedSAFE, there does not appear to be a disparity in the use of guideline directed medical therapy for HFrEF based on race. However, there does seem to be low utilization of hydralazine and isosorbide dinitrate in black or patients with HFrEF that is not unique to VA. Providers have an opportunity to evaluate African American patients with HFrEF for consideration of treatment with hydralazine and isosorbide dinitrate, as appropriate, to improve patient outcomes as per recommendations in clinical practice guidelines.

For more information & references, refer to Hydralazine and Isosorbide Dinitrate in African Americans with HF: Recommendations for Use, Dec. 2016 <https://vaww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/Clinical%20Recommendations/Hydralazine%20and%20Isosorbide%20Dinitrate%20in%20African%20Americans%20with%20Heart%20Failure,%20Clinical%20Recommendations.docx>

Direct Oral Anticoagulants (DOACs) In Obesity

The PBM DOAC CFU documents have been updated to include information on the use of DOACs in obesity, recognizing the recent guidance from the International Thrombosis and Haemostasis (ISTH) (link: <http://onlinelibrary.wiley.com/doi/10.1111/jth.13323/epdf>) and the Anticoagulation Forum Guidance in venous thromboembolism (VTE) treatment. New under the Issues for Consideration Section:

Obesity: Very limited data are available on the use of DOACs in extremes of body weights. Some pharmacokinetic and pharmacodynamic data have found modest effects of body weight extremes on DOAC exposure, but the clinical relevance is unknown. Subgroup analysis of obese patients from the pivotal phase 3 DOAC trials suggests that DOACs generally appear to be safe and effective; however, data are limited. The International Society on Thrombosis and Haemostasis (ISTH) guidance on the use of DOACs in obese patients (2016) suggests not using DOACs in patients with a body mass index (BMI) >40 kg/m² or weight of >120 kg. Similarly, the Anticoagulation Forum VTE Treatment Guidance (2016) advises limiting DOAC use to situations where warfarin is not an option in patients at extremes of weight (e.g., >120 kg or BMI ≥35 kg/m²). VA PBM recommends that when a DOAC is being considered in such patients, a shared decision making approach should be utilized with information provided on the limited data regarding the efficacy and safety of these agents in extremes of body weight and recommendations of some groups against use in this situation.

Article Submitted by: Lisa Longo, PharmD, BCPS National PBM Clinical Pharmacy Program Manager-PBM Formulary Management

PACT PEARLS

Editor's Note: This new section to the Ez Minutes is aimed at communicating helpful information that is of particular interest to any PACT Provider

- Requests for DOACs in the setting of obesity is to be adjudicated locally with consideration of patient preference and co-morbidities using a shared decision making approach. (Read more details above)
- There is no preferred agent for VTE treatment, but considerations for certain agents based on renal function, bleeding risk, desire for oral or injectable initial therapy should be made using a shared decision making approach.
- Consider formulary and less costly nonformulary alternatives prior to betamethasone dipropionate spray for the treatment of mild to moderate plaque psoriasis.
- When appropriate, consider hydralazine and isosorbide dinitrate in African American patients with heart failure and reduced ejection fraction. (Refer to Page 2 for details)

OTHER ANNOUNCEMENT

All HCV Direct-Acting Antivirals (DAAs) CFUs (i.e., Harvoni/Epclusa, Daclatasvir, Simeprevir, Viekira/Technivie) were updated to include the recently published FDA's boxed warning regarding HBV reactivation.

MONTHLY PBM-MAP-VPE Webinars (3rd Tues of the month)

Next webinar Series: **Statistics 101: Demystifying Statistics for the Clinician - (3 part Series)**

Dr. Emily Oien, PharmD, BCPS returns for the 5th consecutive year to present this series. Content is great for new residents (medical/pharmacy), board certification study groups, and any health professionals needing a primer on STATS!

2/21/17 @ 3:10 ET: Part 1: Direct TMS Links (register in TMS by 2/20/17)

ACPE / ACCME accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part I](#)

ACPE - T accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part I for Technicians](#)

3/21/17 @ 3:10 ET: Part 2: Direct TMS Links (Register in TMS by 3/20/17)

ACPE / ACCME accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part II](#)

ACPE - T accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part II for Technicians](#)

4/18/17 @ 3:10 ET: Part 3: Direct TMS Links (Register in TMS by 4/17/17)

ACPE / ACCME accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part III](#)

ACPE - T accreditation: [STATISTICS 101: Demystifying statistics for the clinician Part III for Technicians](#)

Starting January 2017: New start time: 3:10 PM ET for all webinars

Dial in VANTS: 1-800-767-1750 Access Code 49792#

Adobe Connect Meeting Link: <http://va-eerc-ees.adobeconnect.com/pbm-monthly-webinars/>

All webinars are accredited for ACPE, ACPE-T, ACCME, and ACCME-NP unless specified

Mark Your Calendar for these Future Webinars:

May 16th: Regulatory Issues in Pharmacy Practice

June 20th: Update on Hepatitis C